

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Cornelius Marius Timmers et al.

Application No.: 10/540,335

Conf. No.: 8737

Filed: January 10, 2006

Art Unit: 1623

For: TETRAHYDROQUINOLINE DERIVATIVES  
AND THEIR USE AS FSH RECEPTOR  
MODULATORS

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Examiner: Layla Bland

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT  
DETERMINATION UNDER 37 CFR §1.705(B)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Allowability issued August 14, 2009, Applicants respectfully request reconsideration of the Patent Term Adjustment of 0 days noted on page 3 of the Notice, and request that it be corrected to 80 days. The present request, being filed along with the issue fee transmittal, is timely. 37 C.F.R. §1.705(b).

The office is authorized to charge deposit account no. 50-4205 the required fees set forth in 37 C.F.R. §1.18(e) (**\$200**) and 37 C.F.R. §1.705(b)(1).

Applicants respectfully submit that the correct Patent Term Adjustment is 80 days. The basis upon which Applicants request reconsideration of the patent term adjustment is as follows (for details see attached AIPA Term Calculation Report utilizing Professor Kayton's patent Term® on line program):

1. Under the 14-Month Rule [(§1.703(a)] the present application was filed on January 10, 2006 and the First Action was mailed May 2, 2007. Accordingly under the 14-Month Rule the period of adjustment for the USPTO delay is 53 days which is also reflected in the Patent Term Adjustment History.

2. Under the 3-Month Rule [(§1.704(b)], a period of adjustment of 17 days of Applicant delay has been calculated from the Final Action mailed February 20, 2008 to the date of Reply to this Action, i.e., the Notice of Appeal mailed June 6, 2008, as is also reflected in the Patent Term Adjustment History.

3. Under the 3-Month Rule [(§1.704(b)], a period of adjustment of 60 days of Applicant delay has been calculated from the Non-Final Action mailed December 5, 2008 to the date of Reply to this Action, May 4, 2009, as is also reflected in the Patent Term Adjustment History.

4. However, should a patent issue after June 20, 2008 (three years from the June 20, 2005 date of commencement under 35 U.S.C. §371(b) in an international application), adjustment of the patent term pursuant to 35 U.S.C. §154 (b)(1)(B) [(§1.703(b), stipulating issuance of a patent within three years of the application filing date] would be implicated based upon the Wyeth et al. v. Dudas ruling recently published (No. 07-1492 D.D.C. September 30, 2008). Assuming an estimated issue date of February 23, 2010, it is respectfully submitted that the period of adjustment for USPTO delay (in accordance with the ruling in Wyeth et al. v. Dudas) begin on the day after the three year period, June 20, 2008 (see attached AIPA Term Calculation Report utilizing Professor Kayton's patent Term® on line program) and end on the aforementioned estimated issue date, which is a period of adjustment due to USPTO delay of 104 days. In addition, with respect to the three-year rule, it is noted that the Notice of Appeal mailed June 6, 2008 was considered to be withdrawn in view of the Request for Continued Examination mailed October 3, 2008. Accordingly, it was believed that the exclusion rule pertaining to appellate review [(37 C.F.R. 1.703(b)(4)] was not applicable.

5. Accordingly, Applicants respectfully submit that the patent term adjustment period is the total days debited the USPTO, 157 days, minus the total number of days debited Applicants, 77 days, to yield a total patent term adjustment of 80 days ((see attached AIPA Term Calculation Report utilizing Professor Kayton's Patent Term on line program).

The present application is not subject to a terminal disclaimer [37 C.F.R. §1.705(b)(2)(iii)].

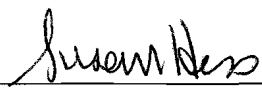
Applicants reserve the right, under 37 C.F.R. §1.705(d), to request further revisions to the patent term adjustment, should the Office fail to note the revised patent term adjustment on the face of any patent issuing from the present application, or fail to timely issue any patent issuing from the present application.

Early and favorable action is earnestly solicited.

Dated: November 12, 2009

Respectfully submitted,

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Attachment  
104451\_1.DOC

# AIPA Term Calculation Report

| APPLICATION INFORMATION |   |                    |  |
|-------------------------|---|--------------------|--|
| Docket Number:          | 2002.749US  | User Name:         | Hess, Susan                                      |
| Application Number:     | 10/540,335  | Firm/Company Name: | Organon, a part of Schering-Plough               |
| Filing Date:            | 12/16/2003  | User Comments:     |  |
| Title/Inventor(s):      | TETRAHYDORQUINOLINE DERIVATIVES AND THEIR USE AS FSH RECEPTOR MODULATORS; Cornelis Marinus Timmers, Oss, (NL) |                    | Calculation Generated: 11/10/2009 04:46:00 PM ET |

| AIPA TERM CALCULATION SUMMARY   |                    |
|---|--------------------|
| Earliest Referenced Application under 35 USC § 120, 121, or 365(c):   | 12 / 16 / 2003     |
| International Filing Date:  | 12 / 16 / 2003     |
| Net Adjustment Credits:   | 157 Days           |
| Net Adjustment Debits:  | 77 Days            |
| Patent Term Adjustment:   | 80 Days            |
| AIPA Patent Term End Date:  | 03 / 05 / 2024 (1) |
| (1) Assumes payment of all maintenance fees, no intervening acts, and no 35 USC 156 regulatory extensions. Terminal disclaimer(s) filed in this case, if any, may result in an earlier term end date. Without adjustment, the term would end on 12/16/2023. |                    |

| COMPARISON TO USPTO PAIR PTA TAB (2)<br>(Based on PAIR Data from 11/10/2009)   |              |                  |            |
|--|--------------|------------------|------------|
|  | PAIR PTA Tab | Your Calculation | Comparison |
| Credit Days (USPTO Delay):   | 53           | 157              | ×          |
| Debit Days (Applicant Delay):  | 77           | 77               | Match      |
| Total Patent Term Adjustment Days:   | 0            | 80               | ×          |
| (2) Comparison is shown for USPTO Delay, Applicant Delay, and Total Patent Term Adjustment fields displayed on USPTO PAIR Patent Term Adjustments (PTA) tab on 11/10/2009. See the full PAIR PTA tab, file wrapper (e.g., Notice of Allowance, PTA-related petitions), and issued patent for complete information on USPTO-calculated PTA. |              |                  |            |

| RULE CALCULATION SUMMARY (3)   |   |  |                    |                |                 |
|--|---|--|--------------------|----------------|-----------------|
| Event  | Rule Invoked  | Related Event  | Exclusion Days (4) | Debit Days (5) | Credit Days (6) |
| A<br>06/20/2005<br>National Stage<br>Commenced under 35<br>USC 371(b) or (f) | <b>3-Year PTO Issue of Patent</b><br><br>PTO must issue a patent within 3 years (not including exclusions) after the date on which the application was filed under 35 USC 111(a) or the national stage commenced under 35 USC 371(b) or (f) in an international application. Period of adjustment (credits) begins on the day after the date that is 3 years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 USC 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the listed exclusionary periods. 35 USC 154(b)(1)(B); 37 CFR 1.702(b), 1.703(b).  | <i>Issue Date:</i><br>02/23/2010<br>Issue Date   |                    |                | 104             |
| B<br>12/20/2005<br>Notice of DO/EO<br>Missing<br>Requirements                | <b>3-Month Applicant Response to Notice or Action</b><br><br>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).<br><br>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).<br><br>You have indicated that no 1.705(c) Showing of Due Care was made. | <i>Applicant Response:</i><br>01/10/2006<br>Oath or Declaration<br>Filed (Original or<br>Supplemental) |                    | 0              |                 |
| C<br>01/10/2006<br>Application Fulfilled<br>Requirements of 35<br>USC 371    | <b>14-Month PTO First Action</b><br><br>PTO must mail a notification under 35 USC 132 or a notice of allowance under 35 USC 151 not later than 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 in an international application. Period of adjustment (credits) begins on the day after the date that is 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 and ending on the date of mailing of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(i); 37 CFR 1.702(a)(1), 1.703(a)(1).   | <i>First PTO Action:</i><br>05/02/2007<br>Non-final Action   |                    |                | 53              |

|   |  |  |  |   |  |
|---|--|--|--|---|--|
| <b>D</b><br>05/02/2007<br>Non-final Action                                | <p align="center"><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p>  | <p align="center"><i>Applicant Response:</i></p> 08/01/2007<br>Reply after Non-final Action under 37 CFR 1.111 |  | 0 |  |
| <b>F</b><br>08/01/2007<br>Reply after Non-final Action under 37 CFR 1.111 | <p align="center"><b>4-Month PTO Response to Applicant Reply</b></p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(c) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2),(3).</p> <p align="center"><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p> | <p align="center"><i>PTO Response:</i></p> 09/11/2007<br>Non-final Action                                      |  | 0 |  |
| <b>F</b><br>09/11/2007<br>Non-final Action                                | <p align="center"><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p>  | <p align="center"><i>Applicant Response:</i></p> 12/11/2007<br>Reply after Non-final Action under 37 CFR 1.111 |  | 0 |  |
| <b>G</b><br>12/11/2007<br>Reply after Non-final Action under 37 CFR 1.111 | <p align="center"><b>4-Month PTO Response to Applicant Reply</b></p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(c) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2),(3).</p>   | <p align="center"><i>PTO Response:</i></p> 02/20/2008<br>Final Rejection                                       |  | 0 |  |

|    |  |   |  |     |    |    |
|----|--|---|--|-----|----|----|
| II | 02/20/2008<br>Final Rejection  | <p align="center"><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p> | <p align="center"><i>Applicant Response:</i></p> <p align="center">06/06/2008<br/>Notice of Appeal to<br/>Board of Patent<br/>Appeal and<br/>Interferences</p> |     |    | 17 |
| I  | 10/03/2008<br>Request for Continued Examination under 35 U.S.C. 132(b) | <p align="center"><b>Exclusion for Continued Examination</b></p> <p>3-Year PTO Issue Requirement does not include the period consumed by continued examination of the application under 35 USC 132(b), beginning on the date on which a request for continued examination of the application under 35 USC 132(b) was filed and ending on the date the patent was issued. 35 USC 154(b)(1)(B)(i); 37 CFR 1.702(b)(1), 1.703(b)(1).</p>   | <p align="center"><i>Issue Date:</i></p> <p align="center">02/23/2010<br/>Issue Date</p>   | 509 |    |    |
| J  | 12/05/2008<br>Non-final Action   | <p align="center"><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p> | <p align="center"><i>Applicant Response:</i></p> <p align="center">05/04/2009<br/>Reply after Non-final<br/>Action under 37 CFR<br/>1.111</p>                  |     | 60 |    |
| K  | 05/04/2009<br>Reply after Non-final Action under 37 CFR 1.111          | <p align="center"><b>4-Month PTO Response to Applicant Reply</b></p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(c) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2), (3).</p>   | <p align="center"><i>PTO Response:</i></p> <p align="center">08/14/2009<br/>Notice of Allowance<br/>under 35 USC 151</p>                                       |     |    | 0  |

### 3-Month Applicant Response to Notice or Action

|  |   |   |     |   |  |
|--|---|---|-----|---|--|
| <p>08/14/2009<br/>Notice of Allowance under 35 USC 151</p>   | <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p> | <p><i>Applicant Response:</i><br/>11/14/2009<br/>Issue Fee Payment under 35 USC 151</p> |     | 0 |  |
| <p>11/14/2009<br/>Issue Fee Payment under 35 USC 151</p>   | <p>PTO must issue a patent not later than 4 months after the date on which the issue fee was paid under 35 USC 151 and all outstanding requirements were satisfied. The period of adjustment (credits) begins on the day after the date that is 4 months after the date the issue fee was paid and all outstanding requirements were satisfied and ends on the day the patent issues. 35 USC 154(b)(1)(A)(iv); 37 CFR 1.702(a)(4), 1.703(a)(6).</p> <p><b>4-Month PTO Issue of Patent</b></p>   | <p><i>Issue Date:</i><br/>02/23/2010<br/>Issue Date</p>                                 |     | 0 |  |
| Total Exclusion, Debit, and Credit Days:   |   |   |     |   |  |
| Overlap Days (7) :   | 509   | 77  | 157 |   |  |
| Net Exclusion, Debit, and Credit Days:   | 0   | 0   | 0   |   |  |
| Patent Term Adjustment Days (8) :  | 509   | 77  | 157 |   |  |
| <p>(3) Calculations of Debit, Credit, and Exclusion Days are determined by the rule assignments, assignments of related events, and analysis options in the Apply Term Rules tab. The patent professional using this system is responsible for reviewing and updating the Apply Term Rules tab to ensure all data is complete, correct, and consistent with their judgment and interpretation of applicable legal authority.</p> <p>(4) Exclusion Days are periods which are not included in determining the end of the 3-year period after the date on which the application was filed under 35 USC 111(a), or the national stage commenced under 35 USC 371(b) or (f) in an international application, used to determine credits under the 3-Year PTO Issue of Patent rule. See 35 USC 154(b)(1)(B)(i)-(iii); 37 CFR 1.702(b)(1)-(5), 1.703(b)(1)-(4).</p> <p>(5) Debit Days are days where grounds for reduction of period of adjustment of patent term exist. See, e.g., 37 CFR 1.704. Debit Days are sometimes referred to as Applicant Delay.</p> <p>(6) Credit Days are days where grounds for adjustment of patent term exist. See, e.g., 37 CFR 1.702, 1.703. Credit Days are sometimes referred to as USPTO Delay.</p> <p>(7) To the extent credit periods overlap other credit periods, debit periods overlap other debit periods, or exclusion periods overlap other exclusion periods, overlaps are subtracted so that each calendar day generates at most one credit day, one debit day, and one exclusion day.</p> <p>(8) Patent Term Adjustment Days equals Net Credit Days minus Net Debit Days, but is not less than zero.</p> |   |   |     |   |  |